



case study:

i3 ONCOLOGY REWRITES PROTOCOL, RETRAINS SITES TO MEET GOALS IN METASTIC BREAST CANCER STUDY

Challenge: Recover a struggling program.

A sponsor was struggling with a Phase II metastatic breast cancer study and identified i3 to take over from another CRO. Because of basic problems with the protocol, the investigative sites were challenged with interpreting the protocol requirements consistently, as well as the documentation required in the case report form. This led to site frustration, lack of patient enrollment, and poor data quality. The program needed a focused protocol review and a redesigned CRF to put the study back on track.

Solution: Understand the stumbling blocks.

i3 Oncology conducted an intensive internal Q&A session and discussed every aspect of the protocol and the CRF to anticipate possible questions and misinterpretations that could occur at the sites (i.e., confusion about the eligibility of aromatase inhibitors vs. hormonal therapy). i3 redesigned the CRF, then worked with the sponsors and the sites to “operationalize” the protocol, providing clarification about the subtleties of the CRF.

Results: Sites re-rolled out, enrollment goals met.

i3's in-depth oncology site knowledge helped facilitate training and communication with the sites. Experienced with oncology trials, the i3 data managers were heavily involved in CRF review to ensure the data were as clean as possible. i3 applied their oncology experience to review the protocol, redesign the CRF, maintain the site relationships, and refocus the study to meet the sponsor's enrollment goals.